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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,228	10/06/2000	John Albert Ellis	454313-2340.2	1613

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EXAMINER

FOLEY, SHANON A

33

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/680,228

Applicant(s)

ELLIS ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 17-19, 21, 23-25, 31, 32, 43-50, 52, 54, 55, 62 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 17-19, 21, 23-25, 31, 32, 43-50, 52, 54, 55, 62 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17. 6) ☐ Other: _____

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DETAILED ACTION

In paper no. 32, applicant amended claims 1, 2, 21, 24, 25 and 50. Claims 1, 2, 17-19, 21, 23-25, 31, 32, 43-50, 52, 54, 55, 62 and 63 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 recites the limitation "a DNA vector" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 17-19, 21, 23-25, 31, 32, 43-50, 52, 54, 54, 55, 62 and 63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 12 of U.S. Patent No. 6,391,314.

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(This rejection was made earlier in paper no. 12 and vacated in paper no. 16. However, upon reconsideration of the instant pending claims, which are different from those previously pending, it is determined that an obviousness-type double patenting issue exists between the instant claims and the claims in the patent.)

Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims are drawn to a vector expressing a specific PCV-2 ORF and additional pig pathogens as well as a method of reducing viral load by administering the compositions. US 6,391,314 is drawn to immunological compositions and a method of inducing an immunological response in a porcine subject with a vector expressing a PCV type II antigen. The species of PCV-2 ORFs recited in the instant claims are encompassed by the genus of PCV type II antigens claimed in '314. In addition, the instant method of reducing viral load is encompassed by the immunological response induced by the method in claim 12 of '314.

Claims 1, 17-19, 24 and 25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, 10 and 13-25 of U.S. Patent No. 6,368,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because the intended use of reducing viral load with the instant composition is an inherent feature of the composition. Therefore, the immunological vector composition of '601 comprising the same ORFs as the instant claims also reduces viral load. In addition, since the vector encoding the PCV ORFs in the patent are immunogenic and are expressed in vivo, see claim 14 for example, the pharmaceutically acceptable carrier required by the instant claims is an obvious limitation in the patent claims.

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Claims 1, 2, 17, 19, 24, 25, 31, 32, 47, 49, 50, 54, 55, 62 and 63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6, 9, 10 and 13-26 of U.S. Patent No. 6,497,883.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant specification teaches that PCV-2 ORFs 1 and 2 of Meehan et al. 1998 are identical to the instant PCV-2 ORFs 4 and 13 in the paragraph bridging pages 22-23. Therefore, since the ORFs of US '883 use the designations set forth in the Meehan et al. 1998 reference, see column 4, lines 53-55 for example, the components within the instant vectors and those of '883 are indistinguishable. Therefore, the intended use of reducing viral load is an inherent feature of the canarypox vector compositions of Bublot et al.

Claims 1, 17-19, 21, 23, 24, 25, 31, 32, 43-50, 52, 54, 55, 62 and 63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 9-11 and 14-28 of U.S. Patent No. 6,217,883. Although the conflicting claims are not identical, they are not patentably distinct from each other because the immunogenic composition of US '883 comprise a vector expressing one PCV-2 ORF 1-13 and an additional pig pathogen. The intended use of reducing viral load is an inherent feature of the vector compositions of US '883.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 17, 18 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang et al. (WO 99/29717).

The claims are drawn to a composition comprising a pharmaceutically acceptable carrier and a vector expressing PCV-2 ORF13.

Wang et al. teach a recombinant vector expressing an immunogenic porcine circovirus type II polypeptide encoding ORF6, see claims 7-10. The coding region disclosed for the ORF6 of Wang et al. is identical to the coding region described in the instant specification for PCV-2 ORF13. See page 22, lines 31-34 and page 23, line 6 of Wang et al. and the coding region for ORF13 for PCV-2 strains 1103 and 1121 on page 25 of the instant specification. Wang et al. also teach that nucleic acid sequences expressing the proteins are administered directly to a subject for in vivo translation thereof, see page 38, lines 21-26. Wang et al. do not teach the intended use recited in the claim for reducing viral load. However, this feature would be an inherent property of the composition of Wang et al. because the vector comprises the identical ORF sequence recited in the instant claims.


Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Shanon Foley
March 4, 2003


JAMES HOUSEL 3/10/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600